

# **DRAFT NATIONAL HEALTH SERVICE (CONCERNS, COMPLAINTS AND REDRESS ARRANGEMENTS) (WALES) REGULATIONS 2010**

## **INFORMAL EXPLANATORY NOTE**

These informal notes have been prepared on behalf of the Minister for Health and Social Services by the Welsh Assembly Government, Health and Social Services Directorate General. They provide readers with an explanation of the effect and intention of the above draft Regulations which the Minister intends laying in the near future. The notes need to be read in conjunction with the draft Regulations. They are not, and are not meant to be, a comprehensive description of the Regulations.

A final Explanatory Memorandum will be published alongside the Regulations when they are laid before the Assembly in due course. Part 10 dealing with transitional and consequential provisions and revocations, and the Schedules is not covered below as it is purely technical in nature.

### **Summary**

In summary, these Regulations make new arrangements for the making, consideration and response to concerns notified by persons in respect of services provided in Wales as part of the health service in Wales. A concern is defined as an expression of dissatisfaction, a complaint, a claim for compensation and any issue arising from a patient safety incident.

NHS bodies in Wales, primary care practitioners in Wales and independent providers in Wales must all follow the procedures for receiving, handling and investigating concerns set out in Parts 3, 4 and 5 of the Regulations.

In addition NHS bodies in Wales must, when they receive notification of a concern in accordance with these regulations, consider whether there may be a qualifying liability in tort in respect of qualifying services. If they are of the view that there may be such a liability ie that there is the possibility that the person notifying the concern may have received negligent treatment, they must in accordance with the provisions of Part 6 of the Regulations investigate whether or not there is a qualifying liability in tort for which an offer of redress may be made. Primary care practitioners do not have to consider redress as an undertaking was given that they would not be included in the new arrangements straight away as they are indemnified by medical defence organisations and there are different considerations involved in making them the subject of the redress arrangements.

The Regulations provide for an offer of redress to comprise of the making of an offer of compensation and/or offers of remedial treatment, an explanation of what went wrong, an apology and the making of an action plan to prevent similar incidents occurring again. The Regulations also provide for a patient to receive free legal advice from a solicitor who specialises in clinical negligence claims in order to ensure that he or she is properly informed in relation to any

offer that is made or refusal to make an offer if, on investigation, it is determined that there is no qualifying liability.

Part 7 of the Regulations deals with how redress is to be provided where Welsh NHS bodies enter into arrangements with providers **outside** of Wales for the provision of services. It also covers independent providers in Wales who provide services to Welsh NHS bodies. Further detail of the policy is set out below but, in essence, independent providers in Wales and providers in England are under an obligation in the Regulations to consider whether or not there is or there may be a qualifying liability in respect of services that they have provided under an arrangement with a Welsh NHS body. If they are of the view that there is such a qualifying liability, they are placed under an obligation in the Regulations to refer the case to the relevant Welsh NHS body together with the supporting information that they are required by the Regulations to provide. The Welsh NHS body will then determine whether or not there is a qualifying liability for which an offer of redress should be made.

Similarly, the Regulations place an obligation on Welsh NHS bodies to consider any notification of treatment that may qualify a patient for redress that is received from a provider in Scotland or Northern Ireland with whom they have entered into an arrangement for the provision of services. The Welsh NHS body will then have to determine whether or not there is a qualifying liability for which an offer of redress should be made. Due to differences in our legal powers, in respect of bodies in Scotland and Northern Ireland, the Regulations do not place any obligations on such Scottish or Northern Irish providers to consider whether or not there may be a qualifying liability in respect of services that they have provided and to provide information to the Welsh NHS body. Instead, the intention is to place such obligations on Scottish and Northern Irish bodies in commissioning contracts.

## **PART 1 – GENERAL (REGULATIONS 1 – 3)**

*Regulation 2* defines words and phrases that are used throughout the body of the regulations.

*Regulation 3* sets out the general principles that should be followed in the management of all concerns. This is an important section as this makes clear what people can expect from the process and how they will be treated. It also provides for a person within the organisation that is the subject of a concern to act as contact throughout the handling of a concern.

## **PART 2 – DUTY TO MAKE ARRANGEMENTS FOR THE HANDLING AND INVESTIGATION OF CONCERNS (REGULATIONS 4 – 9)**

*Regulation 4* places a duty on responsible bodies to make arrangements for the effective handling and investigation of concerns.

*Regulation 5* says that information in a variety of formats will have to be provided about the arrangements. This is to ensure that there is equitable access to the arrangements and that people are not deterred from coming forward. The details will be covered in guidance but the intention is that the needs and requirements of various sectors of the community should be provided for and reflected in information about the arrangements (e.g. the needs of older people; children and young people; people with mental health problems; people with learning disability; people with physical disability including sensory impairment; the BME community; the LBG community). We will also make clear in guidance that primary care practitioners will be provided with relevant leaflets and materials via their Local Health Boards and will not have to produce their own.

*Regulation 6* stipulates that responsible bodies must designate someone to take a strategic overview of the arrangements to ensure that they are being operated properly. For NHS bodies (Local Health Boards and NHS Trusts), this will be a non-officer or non-executive member.

*Regulation 7* ensures that responsible bodies have identified a senior person in an executive role to have responsibility for the effective day to day operation of the arrangements.

*Regulation 8* requires the appointment of a senior investigation manager to oversee the investigation process and other matters relating to the handling of concerns.

*Regulation 9* ensures that staff involved in the handling and investigation of concerns are appropriately trained.

### **PART 3 – NATURE AND SCOPE OF THE ARRANGEMENTS FOR HANDLING CONCERNS (REGULATIONS 10 – 16)**

*Regulation 10* says that responsible bodies must deal with concerns in accordance with the Regulations, so long as the concern is notified in accordance with the Regulations; by a person who is able to notify a concern; about a matter which may be the subject of a concern and within the period specified by the regulations for notifying a concern

*Regulation 11* allows for a complaint to be made in a number of ways, including verbally, if necessary.

*Regulation 12* sets out who can raise a concern. This includes patients or people acting on their behalf, a member of staff, a Board member or partner of a responsible body. The Regulation goes on to provide that children and young people may raise concerns on their own behalf and that they must be provided with assistance to do so if they require it. Parents may still complain on behalf of their child if there are reasonable grounds for the parent to notify the concern rather than the child. Normally a parent will notify a complaint where a child lacks the understanding to be able to make an effective

complaint himself or herself (even with the assistance of trained advocates). Members of staff can also raise concerns about incidents, however, it is important to point out that this is not the same as a “whistle blowing” policy, although the arrangements may well have some overlap. This will be clarified further in guidance but the general position is that if a member of staff reports an incident and initial investigations reveal that there may be a conduct issue relating to another member of staff then the relevant HR policies may then be triggered. *Regulation 12(7)* requires the NHS body to advise the patient or their representative when a concern has been reported by a member of staff and if the investigation reveals that there has been moderate or severe harm or death.

*Regulation 13* sets out that a concern can be notified about any matter relating to a Welsh NHS body, a primary care provider in Wales or independent provider in Wales. It also provides that a Local Health Board can investigate a concern about a primary care provider in Wales. However, a Local Health Board cannot make any determination in respect of the liability of a primary care provider and this is set out in *Regulation 23(2)*.

*Regulation 14* provides for those matters which are excluded from consideration under the arrangements. In particular, concerns relating to matters which are or which become the subject of legal proceedings will not be dealt with under the arrangements. This is because in those cases, the patient has chosen to take a different route for the resolution of their concern. Also, *Regulation 14(1)(j)* excludes concerns about individual patient funding requests, as these will be dealt with by a different process.

*Regulation 15* sets out the time limits which apply. A general 12 month time limit will apply for raising concerns. However, regulation 15(2) provides that the 12 month time limit will not apply if the responsible body believes that the person notifying the concern had good reason for not notifying the incident sooner and, notwithstanding the delay, it is still possible to investigate the concern effectively. Regulation 15(3) provides that a concern may not be notified three or more years from the date of the incident complained about or three or more years from the date that the patient became aware of the matter which is the subject of the concern. This “endstop” has been inserted to make the absolute final time limit for notifying a concern consistent with the limitation period for the majority of clinical negligence claims.

*Regulation 16* allows for the withdrawal of concerns at any time, but provides that the responsible body may continue to investigate, if it felt that it was necessary to do so.

#### **PART 4 – CONCERNS WHICH INVOLVE OTHER RESPONSIBLE BODIES (REGULATIONS 17 – 21)**

*Regulation 17* sets out how a concern should be handled if it covers more than one responsible body – i.e. Welsh NHS bodies, primary care providers in Wales and independent providers in Wales.

*Regulations 18, 19, 20 and 21* cover situations where a concern about a primary care practitioner is raised with a Local Health Board. These Regulations allow Local Health Boards to consider whether it would be appropriate for it to investigate a concern, or whether the matter should be referred back to the primary care provider. It also makes clear that if the primary care provider has already responded to a concern, the Local Health Board would not seek to reopen the matter.

## **PART 5 – HANDLING AND INVESTIGATION OF CONCERNS (REGULATIONS 22 – 24)**

*Regulation 22* sets out what must happen before the investigation begins, in terms of acknowledgement of the concern, the offer of a discussion about how the concern will be handled and what support might be needed.

*Regulation 23* describes the steps to be taken in handling and investigating concerns, such as an initial grading, whether clinical advice is required, whether mediation or facilitation might be employed to help resolve the concern and the consideration of the likelihood of any qualifying liability. The consideration of any qualifying liability only applies to Welsh NHS bodies (i.e. Local Health Boards and NHS Trusts). *Regulation 23(2)* makes clear that if a Local Health Board is investigating a concern about a primary care provider, it will not consider qualifying liability in such a case.

*Regulation 24* sets out what must be included in the final response to an investigation of a concern and the timescales which apply. Regulation 24 does not apply where a Welsh NHS body believes that there is or there may be a qualifying liability in tort. In those circumstances a Welsh NHS body must make an interim response to the concern in accordance with regulation 26. The content of the interim response is set out at *Regulation 26*.

## **PART 6 – REDRESS (REGULATIONS 25 – 33)**

*Regulation 25* sets out a general duty on Welsh NHS bodies to consider redress.

*Regulation 26* sets out what must be contained in an interim response where the initial investigation reveals that there may be a qualifying liability in tort, and the timescales which apply.

*Regulation 27* provides for the forms that redress can take.

*Regulation 28* sets out that redress will not be available if the matter is or has been the subject of civil proceedings.

*Regulation 29* sets a global limit of £40,000 for any award of damages made under the redress arrangements. This encompasses general and special damages and would appear to be a reasonable limit that would encompass the vast majority of the lower value claims that are currently settled by NHS bodies. This is based on a review of claims settled by the NHS over two

financial years where the general damages were limited to £20,000. This global limit has been set to ensure that certain categories of claim, for example under the Fatal Accidents Act 1976, which can attract low levels of general damages (less than £20,000) but potentially very significant levels of special damages are not dealt with under the redress arrangements.

If it becomes apparent that the amount of damages will exceed this amount, then the matter must be taken forward outside of the redress arrangements.

*Regulation 30* makes provision allowing for the limitation period for bringing a civil claim for clinical negligence to be suspended whilst an application for redress is being considered. Limitation is suspended from the date on which a concern is first received by a Welsh NHS body and the regulations make provision for the patient and his or her legal representative to have time consider any offer of redress before the limitation period will start to run again.

*Regulation 31* provides for the findings of the investigation in relation to redress to be recorded in an investigation report.

*Regulation 32* provides for the instruction of legal advisers at certain points in the process, and clinical experts where appropriate. The cost of such legal advice and clinical experts will be borne by the Welsh NHS body and not the patient.

*Regulation 33* sets out the process to be followed if an offer of compensation is to be made.

## **PART 7 – REQUIREMENT FOR PERSONS AND BODIES, OTHER THAN WELSH NHS BODIES, TO CONSIDER REDRESS AND PROCEDURE TO BE FOLLOWED BY A WELSH NHS BODY WHEN IT RECEIVES NOTIFICATION OF A CONCERN IN ACCORDANCE WITH THE PROVISIONS OF THIS PART (REGULATIONS 34 – 48)**

Part 7 of the Regulations deals with how redress is to be provided where Welsh NHS bodies enter into arrangements with providers **outside** of Wales for the provision of services. It also covers independent providers in Wales who provide services to Welsh NHS bodies.

*Regulation 34* sets out the definitions of terms used in this part of the Regulations.

*Regulation 35* provides that where a person or body in England (which includes NHS bodies and independent providers but excludes primary care providers) or an independent provider in Wales receives notification of a concern under a relevant complaints procedure in respect of a service which it has provided, or arranged for the provision of, under an arrangement with a Welsh NHS body it **must** consider whether or not the concern is one to which the redress arrangements could apply. A relevant complaints procedure would, in relation to English bodies, currently be the Local Authority Social

Services and National Health Service Complaints (England) Regulations 2009 and in relation to Welsh independent providers it will be the relevant provisions of the NHS (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2010 when made.

Regulation 35 provides that if such a person or body concludes that a qualifying liability in tort which might give rise to a successful application for redress exists or may exist, it must take the steps outlined in regulation 36.

*Regulation 36* states that the provider body must notify the Welsh NHS body with which it has entered into a contract if it is of the view that a qualifying liability exists or may exist and, after obtaining any necessary consents, provide the Welsh NHS body with :

- Its response to the concern/complaint;
- A copy of relevant medical records;
- A copy of any expert opinion obtained during the complaints investigation;
- A written account of why the provider believes there is or may be a qualifying liability
- The date the concern was received and
- Any other information and assistance that the Welsh NHS body may require.

*Regulation 37* provides that the Welsh NHS body must then acknowledge receipt of the information; advise the person who notified the concern to the provider that the concern has been passed to it to consider whether or not there is a qualifying liability in tort and must determine in accordance with the provisions of Part 7 whether or not an offer of redress should be made to the patient.

This is not covered in the Regulations, as it is not appropriate for it to do so. However, it is intended that any successful application for redress will be settled on the basis of the English provider's liability in tort, or in the case of Welsh independent providers, the Welsh body's liability in tort. It is considered that this is appropriate as the law of tort is the same in England and Wales. This would mean that the waiver that a patient is required to sign in accordance with regulation 48(1)(d) would be in respect of the provider body's liability in tort.

It is anticipated that the Welsh NHS body would pay any settlement costs up front and the legal fees and fees for clinical reports as it is responsible for running the redress arrangement. However, as the claim is being settled on the basis of the provider's liability in tort towards the patient, it is intended to require LHBs and Trusts in Wales to ensure that any commissioning contract with English provider bodies and Welsh independent providers contains provision allowing for the recovery of such costs. This includes the cost of legal fees and any associated clinical fees where an investigation by a Welsh NHS body reveals that there is no qualifying liability in tort.

Regulation 44(5) provides that before making an offer of financial compensation in respect of a concern notified by an English provider or a Welsh independent provider it must consult with and take into consideration the views of such providers.

A fees framework for legal advice to be provided in accordance with the provisions of the Regulations has been proposed under discussion with Claimant solicitors in Wales and representatives of the NHS in Wales and this is attached at the end of this document.

*Regulation 38* provides that if a Welsh NHS body receives a notification from a provider in Scotland or Northern Ireland with whom it has entered into an arrangement for the provision of services that that provider is of the opinion that there may be a qualifying liability in tort in respect of the services that it has provided for the Welsh NHS body, the Welsh NHS body must take the steps outlined in regulation 38. It must acknowledge receipt of the notification, advise the person who notified the concern to the provider that the concern has been passed to it to consider whether or not there is a qualifying liability in tort and must determine in accordance with the provisions of Part 7 whether or not an offer of redress should be made to the patient.

No obligations are placed on providers in Scotland or Northern Ireland under the Regulations. The Regulations do not place obligations on providers in those countries to consider whether there is a qualifying liability in tort and to notify Welsh NHS bodies.

However, it is the policy intention to require Local Health Boards and NHS Trusts in Wales, if they enter into commissioning agreements with Scottish or Northern Irish providers, to insert a provision in the commissioning contract which requires the provider to consider, if it receives a complaint about such services under the terms of the complaints procedure that it is required to operate, whether there is or there may be a qualifying liability in tort. If the provider is of the view that there is or there may be such a liability it must refer the case to the Welsh NHS body to deal with in accordance with the provisions in regulation 38 and the rest of Part 7. It is also intended to place an obligation on Scottish and Northern Irish providers in commissioning contracts to provide the Welsh NHS body with the same information that an English or a Welsh provider is required to send under regulation 36.

Any successful application for redress in respect of the services provided by bodies in Scotland or Northern Ireland would be made on the basis of the Welsh NHS body's own non-delegable duty of care to the Welsh NHS patients who had been sent to Scotland or Northern Ireland for treatment. This means that the compensation and associated legal costs would be met by the Welsh body as the waiver that a patient would be required to sign in accordance with regulation 48(1)(d) would be in respect of the Welsh body's liability towards the patient and not that of the provider body.

*Regulation 39* places a duty on Welsh NHS bodies to offer to meet with the person who notified the concern and then to conduct an investigation.

*Regulation 40* sets out the content of a response to a concern notified in accordance with the provisions of this Part where, following an investigation, it is of the opinion that there is or there may be a qualifying liability in tort. It provides that the Welsh NHS body must produce an interim report, normally within 50 working days from the date on which it received notification of the concern. This is longer than the general requirements set out at *Regulation 26* because of the possible need to obtain further information.

*Regulation 41* sets out what will happen if the Welsh NHS body concludes, following the investigation undertaken in accordance with *regulation 39* that there is no qualifying liability on the part of the provider person or body.

*Regulation 42* provides for the forms that redress can take, which are the same as set out in *Regulation 27*.

*Regulation 43* makes clear that redress will not be available if the matter is or has been the subject of civil proceedings and is the same as *Regulation 28*.

*Regulation 44* is similar to *Regulation 29* and sets a global limit of £40,000 for any award of damages made under the redress arrangements. This encompasses general and special damages. A Welsh NHS body would consult with the English provider or Welsh independent provider before making an offer of redress. If, in the case of a matter referred from a body or person in England, or an independent provider in England or Wales, the amount is likely to exceed the limit shown, then the Welsh NHS body will not proceed to consider an offer outside the Regulations. The agreement of the provider body should be sought on a way forward in these situations and this will be covered in more detail in guidance.

*Regulation 45* is similar to *Regulation 30* and suspends the limitation period from the date on which a concern is first received by the body.

*Regulation 46* is similar to *Regulation 31* and provides for the findings of the investigation in relation to redress to be recorded in an investigation report.

*Regulation 47* mirrors *Regulation 32* provides for the instruction of legal advisers at certain points in the process, and clinical experts where appropriate.

*Regulation 48* is similar to *Regulation 33* sets out the process to be followed if an offer of compensation is to be made.

One issue on which we would, in particular, invite comments in relation to Part 7 is whether the Regulations need to make provision for what happens where a person or body with whom a Welsh NHS body enters into an arrangement for the provision of services decides to sub contract the provision of those services.

## **PART 8 – LEARNING FROM CONCERNS (REGULATION 49)**

*Regulation 49* sets out that responsible bodies must ensure that issues identified in investigations are used to learn lessons and to improve services.

## **PART 9 – MONITORING THE PROCESS (REGULATIONS 50 – 51)**

*Regulation 50* provides for the collection of information about the number of concerns handled and investigated and the subject matter, as well as those considered under the address arrangements.

*Regulation 51* requires an annual report to be produced.

### **Note:**

### **PROPOSED FEES FRAMEWORK FOR LEGAL ADVICE AS REFERRED TO ABOVE**

#### **(Original recommendation of the Putting Things Right Legal Advice working group)**

A composite framework of financial reimbursement for the provision of such advice is felt to be the most appropriate. The framework proposed is as follows;

An hourly rate of £175 exc VAT is charged for Legal advisers time but capped at an upper limit for the first part of the process and thereafter a fixed fee for each step

1) Capped hourly payment to be made for the review of outcome of NHS organisation's investigation and provision of advice to patient.

2) If not concluded at 1) then a fixed fee would be payable for the investigation into liability issues allowing for 2 expert reports, with an additional cost for each agreed extra expert of £350\* where agreed by both the NHS organisation and patient legal adviser

3) If required following 2) a further fixed fee would be payable for investigation of the appropriate value of the claim allowing for 2 expert reports, with an additional cost for each agreed expert of £350\* where agreed by both the NHS organisation and patient's legal adviser.

*4) When there is a need for representation at an Infant Settlement approval hearing, provision to be made for Court fee and fixed counsels fee of £450 exc VAT which may or may not be required. Solicitors to be paid an hourly rate capped at 5 hours work. Those firms engaged in this work will be subject to audit during their*

*involvement in the scheme; hourly rates and fixed fees to be reviewed on a regular basis.*

An indicative cost for each stage is proposed as follows:

	Minimum £	Maximum £
1.	175*	1500*
2.	0	1500* up to 2 experts (+350* per expert if more than 2 experts required and agreed)
3.	0	1500* up to 2 experts (+350* per expert if more than 2 experts required and agreed)
4.	175* + court fee	1325* + court fee Court fee , fixed by Court Counsels fee 450* 875* capped solicitors fees